Accreditation of NGS within ISO 15189

Elke Van Rossen

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BELAC – some numbers

Activities

Number of certificates 2016 (549) (20.09.2016)

- INSP: 134
- QMS: 18
- EMS: 6
- EMAS: 2
- PROD: 29
- MED: 84
- TEST: 228
- PERS: 3
- PT: 8
- GHG: 1
- RM: 1
- CAL: 35

Total: 549 certificates
BELAC – some numbers

Activities: evolution

Op 15.09.2016: 549 certificates, 444 files

+ ±70 %
BELAC – some numbers and facts

NGS in medical laboratories today

- NGS in scope → 15 laboratories (9 N / 6 F) + 2 applications (extension of scope)
- Different platforms used in oncology and hemato-oncology
BELAC – some facts
NGS in medical laboratories today

• NGS audit: clinical biology + bio-informatics

• Increasing demand for extension of scopes with NGS technique

• Questions concerning the accreditation of NGS consortia/networks
  different levels: post-analysis, equipment, cross border, ...

• Contact BELAC to discuss possibilities in advance
1° Sharing of NGS equipment/personnel

Situation:
- NGS equipment is property of lab 1
- Lab 2, 3, ... make use of this equipment
- Multiple legal entities (QS1, QS2, QS3, ...)

Prerequisites:
- trained personnel
  MLT2, 3, ... use NGS in QS2, QS3, ...
  OR MLT1 working for QS2, 3, ...
- equipment is fit for purpose = it suits for tests of lab 1, 2, 3, ...
  ➔ check before use
  ➔ common NGS management
2° Multisite accreditation for NGS equipment

**Situation:**
- NGS equipment is located @ site 1
- Only 1 legal entity = 1 QS
- Multiple sites
Accreditation of NGS network
Different possibilities

3° Continuous subcontracting

**Situation:**
- NGS equipment is property of lab 1
- Multiple legal entities
- Subcontracting of NGS equipment in QS1
- Personnel of L1 in QS1

Exception on Belac 1-03 document

Agreement of the concept by Accreditation Bureau (Sept 2016)

**Prerequisites**

L1 = LE1
- Pre-analysis
- Analysis incl NGS
- Post-analysis

L2 = LE2
- Pre-analysis
- Analysis
- Post-analysis

L3 = LE3
- Pre-analysis
- Analysis
- Post-analysis
Prerequisites to be met in case of continuous subcontracting

- Both laboratories concerned are accredited for ISO 15189
- Exception only approved for the NGS technique or part of it
- Both laboratories concerned have implemented NGS guidelines as published by “Het kankercentrum”
- Only valid for NGS in the field of oncology and hemato-oncology
Accreditation of NGS network
Input for audit team

Key elements to be provided in advance

• Reasons for subcontracting
• Responsibilities (including data-analysis and medical validation)
• Sample flow
• Risk analysis
• Quality control of subcontracted part
• Percentage of subcontracted tests (total accredited tests & specific test)
• Continuous evidence of technical competence for subcontracted activities
Thanks for your attention!
Questions?